

BASIC UNHS PROTOCOLS

Preparation / Initial Screening

1. All parents will be given a parent brochure explaining UNHS prior to screening process. Specific information recommended:
 - Brief description of who does the screening, how it is done, when and where the screening occurs
 - Duration of the screening process, and
 - Reassurance to parents that the procedure is safe and noninvasive, and not painful
2. Parents who refuse to allow their infants to be screened must sign a religious waiver.
3. All newborns except those whose parents sign a religious waiver will receive a physiological hearing screen as soon as practical. Those who do not pass should be re-screened prior to hospital discharge. In all cases the hospital is to complete the rescreen by 14 days of age.

Protocol for Newborns Who Pass UNHS

4. The parents of those infants who pass the initial screen / re-screen will be given a certificate stating that their infant passed. All parents should be advised to consult their PMP if they have concerns regarding development, and / or speech or language progress.
5. Some infants who pass the initial screen or re-screen are at risk of developing a delayed hearing loss. Risk factors include: a family history of permanent childhood hearing loss; congenital infection (e.g. herpes, cytomegalovirus, rubella, syphilis, and toxoplasmosis); and hyperbilirubinemia requiring exchange transfusion.. The parents of these infants shall receive a certificate listing the risk factor and a referral to First Steps. Hearing speech and language development should be monitored by their PMP at periodic preventive health checks. First Steps will monitor them at 9- 12 months.

Protocol for Newborns Who Do Not Pass the UNHS

6. All infants who do not pass initial screen should be re-screened prior to discharge from the birthing institution. In all cases the hospital/birthing institution is to complete the rescreen by 14 days of age.
7. Parents of those infants who do not pass the initial screen / rescreen will receive a certificate indicating the ear(s) with which the infant did not pass. The hospital/birthing institution should also provide them with a copy of the referral to First Steps and PMP, noting what referrals have been made for follow-up. Discuss the results of the screening with the parent(s) explaining the importance of follow-up

It is recommended that "did not pass" rather than "failed" be used in communicating to parents that their infant did not pass the screen. This includes written as well as verbal communication.

The evaluation process should be completed by 3 months and intervention when indicated should begin by 6 months.

BIRTHING INSTITUTION SCREENING REQUIREMENTS AND GUIDELINES

Hospitals/Birthing institutions are required to implement a Universal Newborn Hearing Screening Program to perform hearing screening for every infant born under their care. A summary of program requirements is provided below. In addition, an Implementation Checklist is included in Appendix N as a quick reference to assist hospitals/birthing institutions in establishing their local protocols.

UNHS Program Requirements

1. Distribute parent information brochures prior to screening. Educate parents about the importance of UNHS and advise them of their right to file a religious objection.
2. Conduct Universal Newborn Hearing Screening for all newborns in Indiana using physiologic measures in both ears. Ideally, the methodology used in screening have a false negative rate, i.e. the proportion of infants with significant hearing loss missed by the screening program, of zero. The physiologic method used should detect at least those with significant hearing impairment, i.e. >35 decibels in either one or both ears.
3. Re-screen prior to discharge those infants who do not pass the initial screen.
4. Distribute UNHS certificates to all parents prior to discharge.
5. Implement a referral and follow-up protocol for infants who do not pass the re-screen prior to discharge. This protocol will include distribution of the referral brochure for parents of infants who do not pass, and referral to First Steps, and to the Primary Medical Provider (PMP), if known. The goal is to refer about 4% of infants for follow-up based on hospital screening. In addition, the hospital will also refer infants who pass but have one of the specified risk factors for delayed onset of hearing loss to First Steps, and PMP, if known, for follow-up at 9 - 12 months of age. The goal is to ensure that newborns that have hearing loss at birth are identified by 3 months of age and receive appropriate intervention by 6 months.
6. Report the UNHS Results to ISDH monthly using the report format in Appendix F.

Universal Newborn Hearing Screening prior to discharge, (including the re-screening of those infants who do not initially pass) becomes the standard of care for all Indiana birthing institutions effective July 1, 2000. Indiana Codes 5-10-8-10 and 27-8-24-4 require Hoosier insurance companies to pay for the UNHS.

Time Table for Implementation

Birthing institutions that are currently screening all newborns born in their facilities are required to follow the referral and reporting requirements of this program as soon as this guidance is received. Birthing Institutions that are only providing targeted screening should convert their targeted screening program to universal screening as soon as practical prior to July 1, 2000. Birthing institutions that currently are not screening newborns should also begin UNHS as soon as practical prior to July 1, 2000.

All Indiana birthing institutions no later than 15 August 2000 should submit initial UNHS monthly reports to ISDH.

Responsibilities of Birthing Institutions:

1. Development of the local UNHS Protocol for screening and referral.
2. Implementation of the UNHS Protocol
 - Designate a UNHS Program Director who is responsible for UNHS services.
 - Designate UNHS point of contact for ISDH coordination.
 - Assure that personnel receive appropriate training to implement UNHS.
 - Monitor the UNHS process in order to ensure compliance with referral rate goals.
 - Complete Birthing Institution UNHS Monthly Report.
3. Begin UNHS no later than July 1, 2000.
4. Implement a referral process, which includes the parents, the PMP, and First Steps for all infants who do not pass hearing screening or who are at risk for delayed onset of hearing loss.

Equipment Required

The Indiana State Department of Health does not recommend a particular technique or category of equipment for newborn hearing screening. Hearing screening strategies have been identified by an expert panel convened by the National Institute on Deafness and other Communication Disorders (NIDCD) in 1997. The methods recommended by the panel are Automated Auditory Brainstem Response (ABR) and OtoAcoustic Emissions (OAE) See appendix L for a list of manufacturers and advantages / disadvantages of each method

Quality Assurance

Hospitals and birthing institutions shall monitor their UNHS program regarding quality assurance and quality improvement measures. These measures should include at least the following:

- Referral rates should be approximately 1-4%
- Ensuring that follow-up appointments are made in an appropriate and timely manner.
- Ensuring that screening personnel follow infection control procedures.
- Ensuring that screening results are documented in a timely manner

The UNHS Program Director should review program data such as

- Number of refused screens
- Number of unsuccessful screening attempts
- Number of "did not pass" results
- The effectiveness of individual screeners
- Review the process of how results are communicated to parent(s)/guardian(s)
- Monitor staff members periodically in communicating results of the screening to the parent(s)/guardian(s) if someone other than the audiologist is communicating the results.

It is recommended that audiologists be involved in the process of determining appropriate staff or volunteers for the UNHS program. ISDH realizes that the skill and experience of

the screener is at least as important as the equipment used in achieving acceptable referral rates. Higher false referral rates are expected to occur initially.

Screening Criteria

The criteria for this program are same as for the traditional newborn screening:

- UNHS must be provided to all infants born in Indiana at the earliest feasible time following birth. For the purposes for this law, prior to birthing institution discharge will be considered to be the "earliest feasible time period".
- Unlike other newborn screens that require one or multiple heel-sticks for blood collection, the newborn hearing screening process is painless, non-invasive and has minimum risk.

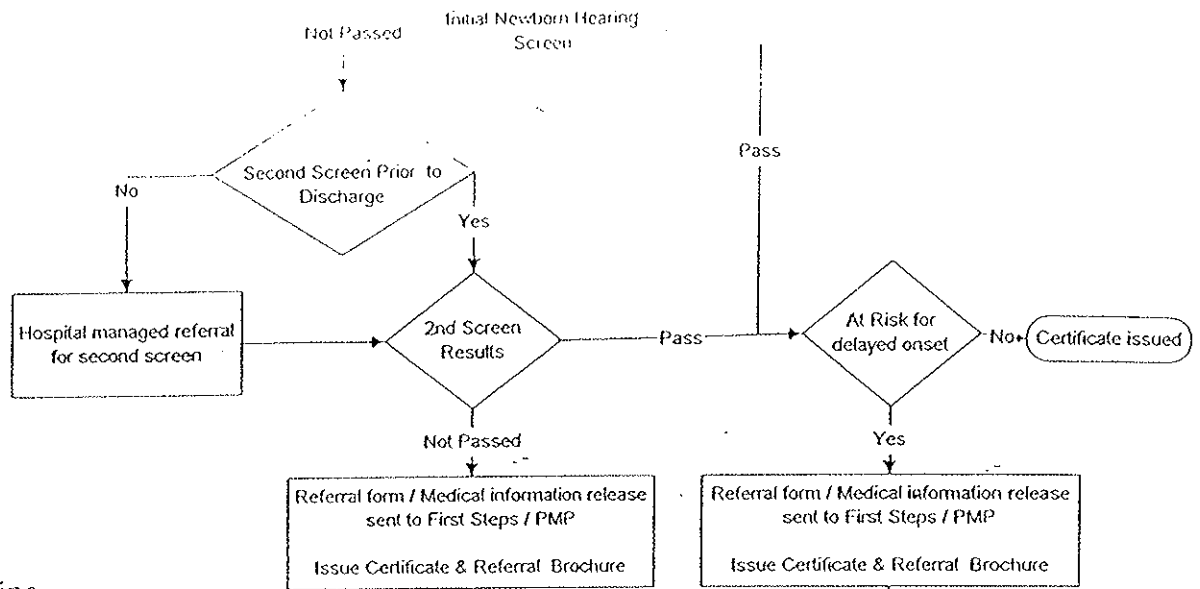
Religious Exemption

UNHS may be refused only if the parent(s) or guardian(s) of the newborn infant object to the screening based upon religious belief. In order to relieve hospitals / birthing institutions of liability from omitting the screening, it is necessary for parents to sign a waiver form documenting that the parent or guardian has refused screening based on religious beliefs. It is recommended that hospitals and birth centers develop an appropriate waiver form. The form shall be in a language that the parent(s)/guardian(s) can understand.

The parent(s) / guardian(s) are key members of the UNHS screening team. They must understand the screening process in order to allow the screen to be performed. They must also understand the limitations of the screen and the possibility that the child can experience hearing loss after discharge. The parent needs to know the signs to watch for and who to turn to if they have a concern about their child's hearing.

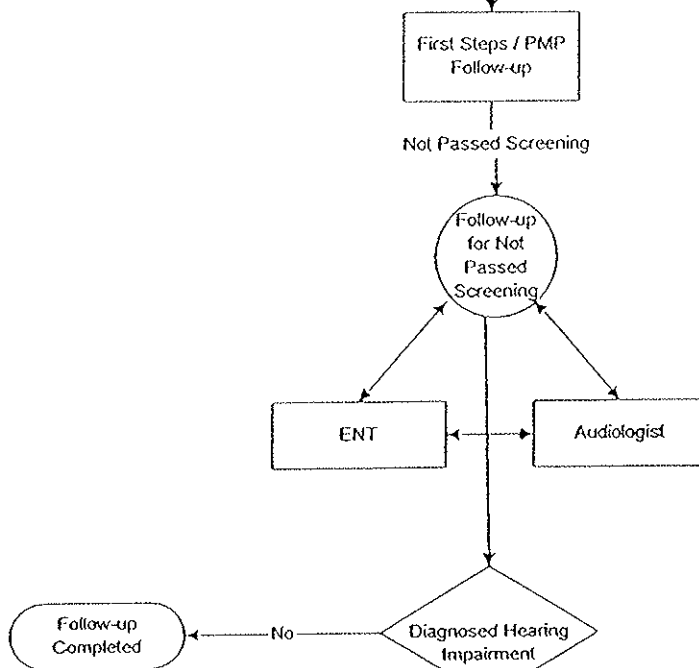
Universal Newborn Hearing Screening Process

Hospital Responsibilities within 14 days



14 day timeline

First Steps Early Intervention Services



3 month timeline

Medical and Early Intervention services continued

